

REMARKS

By this amendment, claims 1 is revised, claims 16 and 17 are canceled, and arguments are made to place this application in condition for allowance. Currently, claims 1, 4, and 6-15 are before the Examiner for consideration on their merits.

In review, claim 1 is revised to include the limitations of claim 17 therein as well as clarify the incise film, the level of the drape, and the relationship between the further fenestration and the means for cover. Claim 16 is canceled as being redundant.

Turning to the prior art rejection, Applicant respectfully traverses the rejection on the grounds that the Examiner does not have the proper articulated reasoning to combine the four prior art references so as to arrive at the invention. The Examiner is merely picking and choosing amongst the prior art without providing the necessary factual underpinnings to support the combination of prior art.

First, none of the prior art addresses the problem sought to be solved by the inventor. As explained in paragraphs [0014-0019] of Applicant's published application, the exact location of an incision site is first determined using a first measurement system. This first measurement is performed in advance of the actual operation.

Then, at the time of surgery, a second measurement is made using a navigation system and a means of reference, wherein the means of reference is located near the operating site, see paragraph [0015]. The means of reference is often infrared emitters and receivers in the form of a three pronged star. The means of reference interacts with the navigation system to ensure that the more precise measurement made in the first measurement is still referenced with respect to the actual operation site.

Often times, the means for reference is not very close to the incision site and is raised from the level of the incision site. This creates a problem with respect to sterility and there are no current surgical drapes, which accommodate both the incision site and the means for reference.

The inventive surgical drape solves this problem by providing a single drape that ensures the sterility of the incision site as well as the means for reference that is not on the level of the incision of the operating site.

None of the cited prior art addresses this problem or provides such a solution. Moreover, the Examiner has committed error in formulating the rejection by making modifications to the prior art without the required and articulated reasoning that *KSR* requires.

The traverse of the rejection is set out below under the headings of the rejection and arguments.

REJECTION

The rejection of claim 1 can be summarized as follows:

- 1) Patnode teaches a two fenestration drape but does not teach a means of cover nor any of the specific features of the means for cover found in claim 1.
- 2) The Examiner also alleges that the second fenestration of Patnode is capable of receiving a means of reference that protrudes from a level of the drape's surface

- 3) Williams is cited to teach a means for cover for an x-ray machine. The means of cover is alleged to be a window 40, which is bound to the top sheet 20 of the drape 10. The drape 10 is tubular in shape and is designed to cover the laser targeting device of Figure 2, with the window 40 positioned to allow the laser beam to emanate from the device while protecting the device from contact with fluids from the operation and protecting the operating site from contaminants from the laser targeting device.
- 4) The Examiner concludes that "it would be obvious for one having ordinary skill in the art at the time of the invention to modify the surgical drape taught by Patnode et al. with the means for cover taught by Williams et al. **because that element is known to make the surgical drape taught by Patnode et al. applicable for use with measurement systems.**" (emphasis added).
- 5) The Examiner admits that the drape of Patnode modified according to the teachings of Williams still fails to have the elongated means of cover or the incise film on the first fenestration.
- 6) The Examiner cites Auerbach to teach a means for cover that has an elongated shape.
- 7) The Examiner alleges that "it would have been obvious for one having ordinary skill in the art at the time of the invention to modify the surgical drape taught by Patnode et al. as modified by Williams et al. with the elongated means of cover taught by Auerbach et al. **because this element**

allows the surgical drape taught by Patnode et al. to be used to create a sterile barrier between a surgical site on an extremity and the remainder of the patient's body. (emphasis added).

8) The Examiner admits that the combination of Patnode, Williams, and Auerbach do not teach the presence of an incise film.

9) The Examiner cites Scrivens to teach a fenestration with an incise film.

10)The Examiner concludes that "it would have been obvious for one having ordinary skill in the art at the time of the invention to modify the surgical drape taught by Patnode et al. as modified by Williams et al. and Auerbach et al. with the means for cover taught by Scrivens **because that element is known to keep the fenestration in its proper position on the body of the patient,** as Scrivens teaches in column 7, lines 9-11." (emphasis added).

Applicant submits that the Examiner has committed a number of errors in formulating the rejection of claim 1 and these errors means that the rejection is not legitimate and could not be sustained on appeal. The errors are identified below under their respective headings.

ERRORS

The rejection does not have the proper reasoning to combine Patnode and Williams.

What the rejection overlooks is that the fundamental aim of Patnode precludes the Examiner's look to the prior art of Williams to modify Patnode.

Referring to Figure 2 of Patnode, the drape of Patnode comprises a main sheet that is made from any flexible substantially fluid impervious sheet material. Main sheet 22 is provided with two apertures 24, shown in phantom. Elastomeric pieces 26 are attached to the main sheet 22 over the area generally corresponding to apertures 24. Elastomeric pieces 26 are provided with first fenestration 28 and second fenestration 29 that will receive the limb of the patient, see col. 3, lines 44 to 49.

In use, the operative limb of the patient is placed through the first fenestration 28, entering from a position below the plane of the drape 20. The operative limb is then placed through the second fenestration 29, entering the second fenestration 29 from a position above the plane of the drape 20. First fenestration 28 is pulled to a location above the operative site on the limb, and the second fenestration 29 is pulled to a location below the operative site on the limb, see col. 3, lines 30-38.

It is clear from this description that **the operative site is not covered by the drape**. Instead, the operative site is located between the first and second fenestrations **above** the plane of the drape, see col. 3, lines 38-40.

The purpose of the elastomeric piece 26 of the fenestrations 28 and 29 of the drape 20 of Patnode is to form an effective seal to isolate the operative site from the remaining portions of the operative limb. **The drape of Patnode is not designed to carry out surgery within the first fenestration 28.**

Further, the second fenestration is not adapted or even capable of being used to receive a means for cover for the reception of a means of reference that protrudes from a level of the surface of the drape at the first fenestration, the means for cover

identifiable by a two or three dimensional measurement system. This is so because beneath the second fenestration is the portion of the patient's limb that is kept isolated from the operative site.

While it is true that Patnode and the invention share two fenestrations, this is where the similarity ends. The use of the fenestrations in Patnode is completely different from the invention. Whereas Patnode uses the fenestrations to isolate parts of the operative limb from the incision site, the invention uses one fenestration for access to the incision site and the other fenestration in combination with a means of cover for a means for reference, with the means for reference interfacing with a measurement system used during surgery. These differences are critical in assessing whether the Examiner's reasoning for modifying Patnode is proper.

Applicant submits that the Examiner's reasoning to modify Patnode using Williams makes no sense and because of this, a prima facie case of obviousness is not established.

Williams discloses a surgical drape with a single fenestration. The drape of Williams is not used to cover an operating site on the body of a patient. It is only adapted to over either end of a C-arm type x-ray machine that would be used at an operating site.

The drape of Williams is completely unrelated to the drape of Patnode. While the Examiner's position that Williams, by himself, teaches a means for cover for a means for reference, wherein the fenestration is bound to the drape, the mere fact that the cover of Williams exists is not determinative of patentability.

Even after the United States Supreme Court's decision in the case of *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), the following legal principles are still valid, having been endorsed by the Supreme Court or having been unaffected by its decision: (1) the USPTO still has the burden of proof on the issue of obviousness; (2) the USPTO must base its decision upon evidence, and it must **support its decision with articulated reasoning** (slip op. at 14); (3) **merely demonstrating that all elements of the claimed invention exist in the prior art is not sufficient to support a determination of obviousness** (slip op. at 14-15); (4) **hindsight has no place in an obviousness analysis** (slip op. at 17); and (5) Applicant is entitled to a careful, thorough, professional examination of the claims (slip op. at 7, 23, in which the Supreme Court remarked that a poor examination reflected poorly upon the USPTO).

The real question is whether the proper articulated reasoning exists to modify Patnode in the manner espoused in the rejection. The Examiner's reasoning is improper since it fails to say why one of skill in the art would apply the means of cover to Patnode. In (4) above, the Examiner's reasoning is "**that element is known to make the surgical drape taught by Patnode et al. applicable for use with measurement systems.**" This reasoning is incorrect. The element of Williams is known to make the drape of Williams (not Patnode) applicable for use with measurement systems. Williams has nothing to do with a drape designed in the manner of Patnode so how does one of skill in the art know that the drape of Williams is applicable to the drape arrangement of Patnode. The Examiner is drawing a conclusion of obviousness without the proper factual basis. What the Examiner has

done is conclude that it would be obvious to use the means of cover of Williams on the second fenestration of Patnode because Williams teaches a means of cover and Patnode does not. This bald conclusion lacks the articulated reasoning required by KSR, i.e., why would one of skill use the known means of cover of Williams on the drape of Patnode. Again, the Examiner is merely identifying a means of cover in the prior art, i.e., Williams, and without any reason to use it with Patnode, concluding that it would be obvious to do so. This is error on the Examiner's part and because of this, a prima facie case of obviousness is not established.

The rejection using Williams and Patnode is also in error since the proposed modification of Patnode cannot meet the firmly bound limitation of claim 1. Claim 1 requires that the means of cover is firmly bound with the drape along the entire perimeter of the second fenestration. Due to the design of the drape of Patnode, it is not possible to modify this surgical drape with the means of cover of Williams. That is, it is not possible to firmly bind any drape along the entire perimeter of the second fenestration of Patnode. Each fenestration of Patnode's drape is provided in a sheet of elastomeric material, which is not able to carry any means of cover, which is elongated with a closed end on the side facing away from the drape so that a means of reference is able to protrude from the level of the drape's surface.

Based on the arguments above, the combination of Patnode and Williams is improper and this taints the rejection to the point that it must be withdrawn. Without the ability to properly include a means of cover for Patnode, the teachings of Auerbach and Scrivens are moot.

Further, neither Auerbach nor Scrivens teach a reason to use the means of cover of Williams with Patnode so that they cannot remedy the flaw in the rejection and produce the invention of claim 1, as amended.

The reasoning used to modify Patnode with Auerbach is flawed.

In the rejection and as quoted in number (7) above, the Examiner admits that the modified drape of Patnode is not elongated and turns to Auerbach to resolve this failing.

Auerbach teaches a drape for surgery like Patnode. The aim of Auerbach is to develop a drape that can accommodate different size extremities. Referring to Figure 1 of Auerbach, a surgical drape 2 for covering operating sites on the body of the patient comprises a sleeve 3 protruding from the level of the drape surface. The sleeve 3 is bound to the drape and extensible so that it can accommodate different length extremities. The sleeve has a closed end 32 on the side facing away from the drape. In use, the drape is positioned on the extremity and the doctor has to create a surgical access opening at any location along the sleeve and around the sleeve to access the extremity. There is no predetermined opening in Auerbach, see col. 6, lines 16-25.

In the rejection, the Examiner says that it would be obvious to modify the drape of Patnode "with the elongated means of cover taught by Patnode et al." Applicant questions as to what type of modification is proposed by the Examiner. The rejection does not say how the modification is made; just that the drape of Patnode is with the sleeve of Auerbach. Applicant submits that the Examiner is again erring by merely

identifying a feature in the prior art and then concluding that just because the feature exists, it can be used with the Patnode drape. Given the way the fenestrations of Patnode are designed, how does one use the elongated cover of Auerbach in the drape of Patnode. The fenestrations of Patnode are designed to seal the limb portions from the operating site. The drape of Auerbach is designed to envelop the limb and permit an incision to be made in the sleeve for surgery. There just is no legitimate reason to pluck the sleeve of Auerbach and use it with one of the two fenestrations of Patnode.

The reasoning used in the rejection is also in error. The Examiner states **“because this element allows the surgical drape taught by Patnode et al. to be used to create a sterile barrier between a surgical site on an extremity and the remainder of the patient’s body.”** Again, the Examiner draws a conclusion without any factual basis. Closely reading the reasoning, the Examiner is saying that the drape of Patnode can be used to create a sterile barrier. Patnode already teaches this concept and Auerbach adds nothing to this fact.

As argued for Williams, Auerbach doesn’t “allow” the drape of Patnode to be used for any purpose. Auerbach teaches a particular kind of drape. The question is whether there is a reason to employ the features of the Auerbach drape in the drape of Patnode. Given that Patnode’s drape is designed to isolate areas that are not being operated on and Auerbach’s drape is for use on the operative site, why take the elongated drape of Auerbach and incorporate into the drape of Patnode, when each drape is for a fundamentally different purpose.

If the Examiner is saying that one of skill in the art could use the Auerbach drape on the incision site in Patnode, this would result in two drapes, the Patnode drape to isolate the limb portions next to the surgical site and the Auerbach drape for the surgical site itself. This combination of two drapes does not product the invention since neither the drape of Patnode nor the drape of Auerbach by themselves have the features of claim 1 as amended. If this is the Examiner's proposed modification, the rejection fails.

If the Examiner is saying that the drape of Patnode can employ the sleeve of Auerbach, this rejection is in error since the proper reasoning for using the sleeve in Patnode does not exist as argued above.

In addition, the same argument made above regarding the impossibility to firmly bond the sleeve of Auerbach along the perimeter of the fenestration of Patnode is made. Again, each of Patnode's fenestrations is provided in a sheet of elastomeric material, which is not able to carry any means of cover, particularly one that is elongated with a closed end on the side facing away from the drape so that the means for reference is able to protrude from the level of the drape's surface.

To summarize, the reasoning supporting the reliance on Auerbach is flawed and this is another reason why the rejection is improper and must be withdrawn.

The reasoning used to modify Patnode with Scrivens is flawed.

In the rejection, the Examiner admits that an incision film is not used in Patnode. Scrivener is cited to show that incision films over fenestrations are known.

Applicant does not dispute the teachings of Scrivener and the use of incision films is already admitted in the application. Referring to Figure 1 of Scrivens, a surgical drape 20 is disclosed that is generally T-shaped in configuration and comprises a main sheet 22 of flexible drapable material. The drape includes a first fenestration 30 through which the surgeon will perform some portions of the surgical procedures and a second fenestration 40 through which the surgeon will perform other portions of the surgical procedure.

Each of the fenestrations 30 and 40 is covered with a closure member which comprises a flexible plastic film. Fenestration 30 is covered with a closure member 70 and fenestration member 40 is covered with a closure member 71. Preferably, the film comprising closure members 70 and 71 is clear so that it can be seen through and is antistatic so as to avoid the buildup of hazardous static electric charges. As will be seen, the closure members 70 and 71 (which are, in fact, incise films) will be adhered to the skin of the patient during the draping procedure. The incise film serves to keep the fenestration in place on the patient and the surgeon makes the required incisions directly through the incise film, see col. 3, lines 28-29 and col. 6, lines 66 to col. 7, line 13.

Clearly, Scrivens does not teach the claimed second fenestration with the means for cover as claimed.

However, the invention is not merely the use of an incision film over a fenestration. Rather, the invention is the combination of the two fenestrations as claimed with the incision film associated with one fenestration and the specially-

configured means for cover for the means for reference as part of the claimed further fenestration. .

One flaw in the rejection using Scrivens is the Examiner's reasoning used to modify Patnode, see number (10) above. In the rejection, the Examiner again takes the approach of citing a known feature of the prior art, i.e., the incision film containing fenestration of Scrivens and observing that just because this exists, it can automatically be used with Patnode. As a reason for modifying Patnode, the Examiner says that the Patnode drape can be "with the means of cover taught by Scrivens because that element (the Scrivens incise film) is known to keep the fenestration in its proper position on the body of the patient."

This reasoning has the same flaw as that pointed out above for the rejection based on Patnode and Williams. That is, instead of saying why one of skill in the art would apply the plastic film of Scrivens to the fenestration of Patnode, the Examiner merely quotes a utility of the film taught by Scrivens. While this teaching may be important from the standpoint of Scrivens, it must also be taken in the context of the fenestrations of Patnode, which are the ones being modified. The col. 7, lines 9-11 passage of Scrivens is followed by another teaching, wherein the incise film is placed on the patient with the incisions made through the film.

In Patnode, the fenestrations are used to allow the limb portions to extend through the fenestrations, with the fenestrations isolating portions of the limbs from the incision site. Since the limbs are designed to pass through the fenestrations in Patnode, why would one of skill in the art employ an incision film over the fenestration? In fact,

one of skill in the art **could not** employ the incision film of Scrivens over the fenestrations of Patnode, since such a modification would defeat the purpose of the fenestrations, i.e., allow the limb to pass through the fenestrations and expose a portion of the limb for surgery while isolating remaining portions.

To recap, the Examiner has not supplied the proper and articulated reasoning to use the incise films of Scrivens on the drape of Patnode. Moreover, even if the Examiner were to insist that an incise film could be used over the fenestrations of Patnode based on Scrivens, the features of the further fenestration are still not present and a prima facie case of obviousness is not established.

Examiner's Comments in Rejection.

On pages 2 and 3 of the Detailed Action, the Examiner provides additional comments over and above the rejection.

One comment concerns whether the drape of Williams is capable of covering a means for reference. The Examiner concludes that it is. Applicant is not arguing the manner in which the Williams drape can be used.

The real question is whether the Examiner has provided the proper and articulated reasoning to modify Patnode with the teachings of Williams. In response to Applicant's argument that the Examiner has not provided the proper reason, the Examiner merely restates the conclusion of obviousness, which is found in number (4) above. As pointed out above, the Examiner's statement that the element of Williams is known to make the surgical drape of Patnode applicable for use with measurement

systems makes no sense. Williams teaches that a drape for an instrument can be made, with the drape having a window so that the drape can function to protect both the patient and the machine as well as allow transmission of the laser. How is this teaching relevant to the surgical drape of Patnode, which is intended to isolate certain portions of the limb from the portion of the limb that is the subject of the operation? There is no connection and no reason for one of skill in the art to employ an instrument drape in Patnode.

If the Examiner is saying that the drape of Williams could be used to drape an instrument that would be used in an operation on a limb that would employ the drape of Patnode, Applicant does not dispute such a position. However, this results in the use of two distinct drapes and does not produce a single drape with all of the features of claim 1.

Remaining Secondary References

The Examiner also relies on other secondary references to reject certain of the dependent claims. Notwithstanding the propriety of these rejections, the other secondary references do not remedy the failing in the rejection of claim 1. Therefore, even if the secondary references were properly combined with the four references discussed above, a prima facie case of obviousness does still not exist against claim 1.

Further, the rejection of claims 6 and 8 based on Greco is in error. Here, the Examiner cites Greco to teach a strap to close the enclosure at its open end around the arm. The Examiner baldly concludes that the drape of Patnode as modified by Williams,

Auerbach, and Scrivens can be “with the means of reduction taught by Greco. As with the other rejections, the Examiner does not explain what is meant by “with the means of reduction” of Greco.

This approach is also error since the mere fact that Greco uses a strap on enclosure does not mean that it can be used on a means of cover according to claim 6. The strap of Greco is designed as a seal for fluid. Why employ this strap in the elongated means of cover of Auerbach? Again, the Examiner is merely citing a feature of the claims that is in the prior art and concluding that it can be used in Patnode without any reason to do so other than its mere existence.

The reason given in the rejection of claims 6 and 8 shares the same flaws as the other reasons used in the rejection. The Examiner alleges that the strap of Greco is known to allow the drape of Patnode to be secured to objects of various sizes. What is known is that the strap allows the enclosure of Greco to be secured to various objects. What also may be known is that the strap of Greco could be used to secure the end of the drape of Patnode that is opposite the fenestration around the limb to form a seal on the end of the drape opposite the fenestration. It could also be known that the strap is used with Auerbach, but Auerbach already has a strap to keep the enclosure on the x-ray machine. This knowledge has nothing to do with controlling the periphery of a means of cover firmly mounted to a fenestration for the purpose of adjusting the size of the cover with respect to a means of reference contained in the cover.

Therefore, the rejection of claims 6 and 8 is improper and must be withdrawn.

Summary

To recap, the Examiner has committed a number of errors in the rejection. Mainly, the Examiner has merely gone out and found various pieces of the drape of claim 1 and baldly concluded that because each of the pieces found in the secondary references of Williams, Auerbach, and Scrivens exist, they can be somehow used in the drape of Patnode such that the invention is produced. This approach violates the mandate made in *KSR* that just because a feature may be found in the prior art does not mean that it can be automatically employed in some other prior art to allege obviousness.

The Examiner has also committed error by failing to realize the impossible nature of bonding a means of cover to the fenestrations of Patnode and this is a further reason that the rejection of claim 1 is improper and must be withdrawn.

The Examiner has also failed to establish a prima facie case of obviousness against claim 6 and its dependent claim.

Since a prima facie case of obviousness has not been established against claim 1 and claim 6, their respective dependent claims are also in condition for allowance by virtue of their claim dependency.

Accordingly, the Examiner is requested to examine this application and pass claims 1, 4, and 6-15 onto issuance.

If the Examiner believes that an interview would be helpful in expediting the allowance of this application, the Examiner is requested to telephone the undersigned at 202-835-1753.

Application No.: 10/562,215

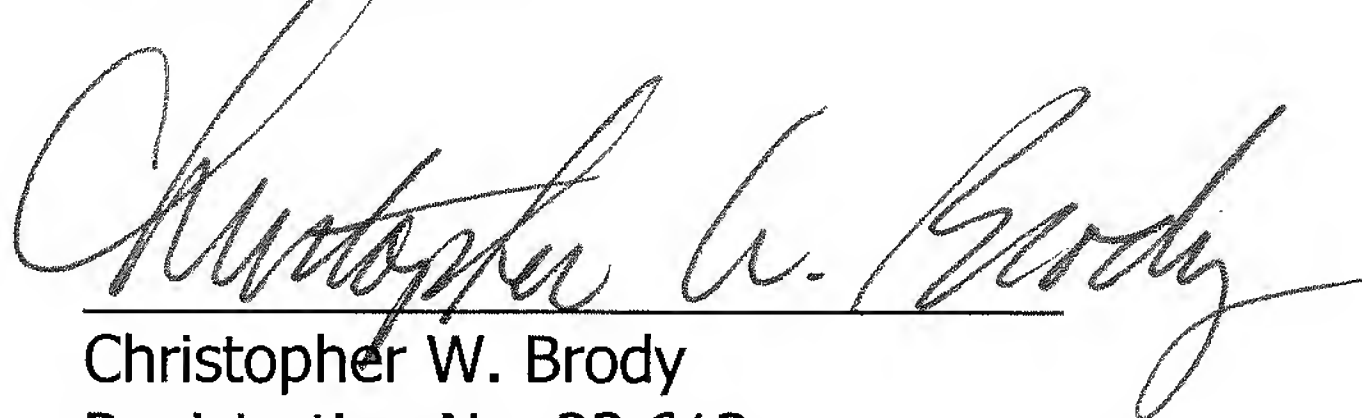
The above constitutes a complete response to all issues raised in the Office Action dated February 2, 2010.

Again, reconsideration and allowance of this application is respectfully requested.

A petition for a three month extension of time is made. Please charge Deposit Account No. 50-1088 the \$555.00 for the three month extension of time.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 50-1088.

Respectfully submitted,
CLARK & BRODY

A handwritten signature in cursive script, reading "Christopher W. Brody", written over a horizontal line.

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